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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
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Louis M Heidelberger			NAJARIAN, LENA		
Reed Smith LLP 2500 One Liberty Place			ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/774,791	NEUMAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Lena Najarian	3626				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>07 March 2006</u> .						
<i>,</i> —	, <del></del>					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 1-9,12-22,24-31,33,34,36,38-40 and 42-91 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-9,12-22,24-31,33,34,36,38-40 and 42-91</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)	4) The leading Commercian	(PTO 413)				
<ul> <li>1) Notice of References Cited (PTO-892)</li> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ul>	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					

#### **DETAILED ACTION**

# Notice to Applicant

1. This communication is in response to the request for continued examination (RCE) filed 3/7/06. Claims 1-9, 12-22, 24-31, 33, 34, 36, 38-40, and 42-91 are pending. Claims 1, 20, 25, 36, 38, 45, 47, and 49 have been amended. Claims 10, 11, 23, 32, 35, 37, and 41 have been cancelled.

# Claim Objections

- 2. The objection to claim 20 is hereby withdrawn due to the amendment filed 11/8/05.
- 3. Claim 51 is objected to because of the following informalities: "entering via a an" should be changed to entering via an" (line 2). Appropriate correction is required.
- 4. Claim 57 is objected to because of the following informalities: there is repetitive language at line 2 (remove "that the"). Appropriate correction is required.
- 5. Claim 64 is objected to because of the following informalities: "communication" should be changed to "communicating". Appropriate correction is required.

# Claim Rejections - 35 USC § 101

6. Claims 45-46 and 84-85 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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For a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention recites a data signal embodied in a transmission medium. A signal per se is not the type of subject matter that is considered statutory. If the signal claim is interpreted as an abstract arrangement "to be transmitted", or as a transmission in transit, rather than a physical signal statically embedded in a physical computer readable medium, the signal claim is considered non-statutory. Since the claimed invention, as a whole, does not produce a useful, concrete, and tangible result, claims 45-46 and 84-85 are deemed to be directed to non-statutory subject matter.

The Examiner suggests Applicant change "transmission medium" to "computer readable medium."

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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- 8. Claims 79-84 and 86-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenblum (US 6,529,801 B1).
- (A) Referring to claim 79, Rosenblum discloses a method comprising:

entering via an electronic device configured to create prescriptions a reason why a prescription of a drug created by the electronic device is to be dispensed as written (see Fig. 29B, abstract, and col. 9, lines 31-36 of Rosenblum; the Examiner interprets the DAW code to be a form of "reason").

- (B) Referring to claims 80-83, Rosenblum discloses the reason being received by a service provider of software for the electronic device (col. 3, lines 6-36 of Rosenblum), the reason being received by a pharmacy (col. 9, lines 41-58 of Rosenblum), forwarding the reason to at least one of a claims processor and a pharmacy benefit management company (Fig. 3 of Rosenblum), and receiving the prescription (col. 2, lines 4-7 of Rosenblum).
- (C) Referring to claim 84, Rosenblum discloses a computer data signal embodied in a transmission medium comprising (col. 3, lines 4-36 and Fig. 2 of Rosenblum):

computer-readable program code for causing the electronic prescription creation device to query whether the user desires to dispense a drug as written (col. 9, lines 10-40 of Rosenblum); and

computer-readable program code for causing the electronic prescription creation device to receive a reason why the drug is to be dispensed as written (col. 9, lines 10-40 and Fig. 29B of Rosenblum).

(D) Referring to claim 86, Rosenblum discloses an apparatus comprising:

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an electronic device configured to create prescriptions (abstract of Rosenblum), the electronic device including means for receiving a reason why a user of the electronic device requests that a drug for a prescription is to be dispensed as written (Fig. 29B and col. 9, lines 10-40 of Rosenblum).

(E) Referring to claim 87, Rosenblum discloses the electronic device further comprising means for including the reason with a prescription created with the electronic device (Fig. 29B and col. 9, lines 10-40 of Rosenblum).

#### Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-50, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Lion (US 6,330,491 B1).
- (A) Referring to claim 1, Goetz discloses a method comprising:

entering via an electronic prescription creation device a prescription for a drug (abstract, lines 1-12 of Goetz; the Examiner interprets "medication management system" to be a form of "prescription creation device");

viewing a drug use evaluation alert on a graphical user interface of the electronic prescription creation device (abstract, lines 19-25 & col. 4, lines 50-52 of Goetz);

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viewing on the graphical user interface a query of whether a user desires to override the drug use evaluation alert;

entering via the electronic prescription creation device an override of the drug use evaluation alert (col. 12, lines 3-10 of Goetz);

transmitting the prescription and override over a network to a prescription processor (col. 12, lines 51-59 and col. 6, lines 22-26 of Goetz);

wherein the prescription processor, upon receipt of the prescription, attempts to process the prescription and actuates a second drug use evaluation, and if a resultant drug use evaluation alert is correspondent to said override of the user, the prescription processor processes the prescription (col. 11, line 52 – col. 12, line 10 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

(B) Referring to claim 2, Goetz discloses viewing on the graphical user interface a plurality of representations each corresponding to a motive for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz; the Examiner interprets "a specific caution note" to be a form of "motive").

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- (C) Referring to claim 9, Goetz discloses selecting via the electronic prescription creation device at least one of the plurality of representations (Fig. 19 & Fig. 20 of Goetz).
- (D) Referring to claim 14, Goetz discloses the prescription being an electronic prescription (Fig. 22 of Goetz).
- (E) Referring to claim 15, Goetz discloses the electronic prescription including information communicating that the user has overridden the drug use evaluation alert (col. 16, lines 42-47 of Goetz; the Examiner interprets "a specific caution note" to be a form of "information communicating that the user has overridden the drug use evaluation alert").
- (F) Referring to claim 16, Goetz discloses the information including the drug use evaluation alert (abstract, lines 29-31 of Goetz).
- (G) Referring to claim 17, Goetz discloses the drug use evaluation alert being:
  - a drug-allergy alert (col. 10, lines 7-9 of Goetz);
  - a drug-drug interaction alert (abstract, lines 29-31 of Goetz);
  - a drug-food interaction alert (col. 4, lines 62-65 of Goetz); and
  - an alcohol conflict alert (col. 4, lines 62-65 of Goetz);
- (H) Referring to claim 18, Goetz discloses entering via the electronic prescription creation device a reason for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz; the Examiner interprets "note" to be a form of "reason").
- (I) Referring to claim 19, Goetz discloses the electronic prescription creation device being a personal digital assistant (col. 5, lines 36-40 of Goetz).

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(J) Referring to claim 20, Goetz discloses a method comprising:

entering via an electronic prescription creation device a prescription for a drug (abstract, lines 8-12 of Goetz);

viewing a drug use evaluation alert on a graphical user interface of the electronic prescription creation device (abstract, lines 19-25 & col. 4, lines 50-52 of Goetz);

entering via the electronic prescription creation device a reason for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz); and

transmitting the prescription and a reason for overriding the drug use evaluation alert over a network to a prescription processor (col. 12, lines 51-59 and col. 6, lines 22-26 of Goetz);

wherein the prescription processor, upon receipt of the prescription, attempts to process the prescription and actuates a second drug use evaluation, and if a resultant drug use evaluation alert is correspondent to said override of the user, the prescription processor processes the prescription (col. 11, line 52 – col. 12, line 10 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

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- (K) Referring to claim 21, Goetz discloses viewing on the graphical user interface a plurality of representations each corresponding to a motive for overriding the drug use evaluation alert, entering via the electronic prescription creation device the reason for overriding the drug use evaluation alert including selecting via the electronic prescription creation device at least one of the plurality of representations (col. 16, lines 42-47, Fig. 19, and Fig. 20 of Goetz).
- (L) Referring to claim 24, Goetz discloses the prescription including an indication that a user has overridden the drug use evaluation alert (col. 16, lines 42-47 of Goetz).
- (M) Claim 25 differs from method claim 1 by reciting "a computer-readable medium having instructions stored thereon" within its preamble. As per these elements, Goetz's medication management system includes a smart card reader and a software application on a personal computer, which reads data from the memory device (col. 5, lines 36-64 of Goetz). As such, it is readily apparent that Goetz's medication management system is controlled by instructions stored upon a computer-readable medium.

The remainder of claim 25 repeats the same limitations of method claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(N) Referring to claim 26, Goetz discloses the instructions when executed by the electronic prescription creation device further causing the electronic prescription creation device to:

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present on the graphical user interface a plurality of motives for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz).

(O) Referring to claim 27, Goetz discloses the instructions when executed by the electronic prescription creation device further causing the electronic prescription creation device to:

receive from the user a reason for overriding the drug use evaluation alert, the reason for overriding the drug use evaluation alert being at least one of the plurality of motives presented on the graphical user interface (col. 16, lines 42-47 of Goetz).

(P) Claim 29 differs from method claim 24 by reciting "a computer-readable medium" within its preamble. As per these elements, Goetz's medication management system includes a smart card reader and a software application on a personal computer, which reads data from the memory device (col. 5, lines 36-64 of Goetz). As such, it is readily apparent that Goetz's medication management system is controlled by instructions stored upon a computer-readable medium.

The remainder of claim 29 repeats the same limitations of method claim 24, and is therefore rejected for the same reasons given above for claim 24, and incorporated herein.

(Q) Referring to claim 30, Goetz discloses the instructions when executed by the electronic prescription creation device further causing the electronic prescription creation device to:

include with the prescription the drug use evaluation alert (col. 16, lines 42-47 of Goetz).

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(R) Claim 31 differs from method claim 14 by reciting "a computer-readable medium" within its preamble. As per these elements, Goetz's medication management system includes a smart card reader and a software application on a personal computer, which reads data from the memory device (col. 5, lines 36-64 of Goetz). As such, it is readily apparent that Goetz's medication management system is controlled by instructions stored upon a computer-readable medium.

The remainder of claim 31 repeats the same limitations of method claim 14, and is therefore rejected for the same reasons given above for claim 14, and incorporated herein.

(S) Referring to claim 33, Goetz discloses the instructions when executed by the electronic prescription creation device further causing the electronic prescription creation device to:

receive from the user a reason for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz).

(T) Referring to claim 34, Goetz discloses the instructions when executed by the electronic prescription creation device further causing the electronic prescription creation device to:

communicate to a workstation via a network the reason for overriding the drug use evaluation alert (col. 16, lines 42-47 & col. 6, lines 1-9 of Goetz).

(U) Referring to claim 36, Goetz discloses the instructions when executed by an electronic prescription creation device cause the electronic prescription creation device to:

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create a prescription for a patient (Fig. 20 of Goetz);

present on a graphical user interface of the electronic prescription creation device a plurality of representations each corresponding to a motive for overriding a drug use evaluation alert (col. 16, lines 42-47 of Goetz); and

receive from a user a selection of one of the plurality of representations; and (Fig. 19 of Goetz)

transmit the prescription and motive for overriding a drug use evaluation alert over a network to a prescription processor (col. 12, lines 51-59 and col. 6, lines 22-26 of Goetz);

wherein the prescription processor, upon receipt of the prescription, attempts to process the prescription and actuates a second drug use evaluation, and if a resultant drug use evaluation alert is correspondent to said override of the user, the prescription processor processes the prescription (col. 11, line 52 – col. 12, line 10 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

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(V) Claim 38 repeats the same limitations of claim 24, and is therefore rejected for the same reason given for that claim.

- (W) Claim 39 repeats the same limitations of claim 33, and is therefore rejected for the same reason given for that claim.
- (X) Referring to claim 40, Goetz discloses the reason being received by a service provider of software for the electronic device (col. 5, lines 56-64 of Goetz).
- (Y) Referring to claim 42, Goetz discloses the indication being received by a pharmacy (col. 6, lines 1-9 of Goetz).
- (Z) Referring to claim 43, Goetz discloses further comprising forwarding the indication to at least one of a pharmacy benefit management company and a claims processor (col.
- 2, lines 22-27 of Goetz; the Examiner interprets "insurance providers" to be a form of "claims processor").
- (AA) Claim 44 repeats the same limitations of claim 40, and is therefore rejected for the same reason given for that claim.
- (BB) Referring to claim 45, Goetz discloses a computer data signal embodied in a transmission medium comprising (Fig. 1, col. 4, lines 17-33, & col. 8, lines 59-65 of Goetz):

computer-readable program code causing an electronic prescription creation device to create an electronic prescription (Fig. 29 and col. 8, lines 52-67 of Goetz);

computer-readable program code causing an electronic prescription creation device to present a user of the electronic prescription creation device a drug use evaluation alert (col. 12, lines 12-21 & 51-59 of Goetz);

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computer-readable program code for causing an electronic prescription creation device to query whether the user desires to override the drug use evaluation alert;

computer-readable program code for causing an electronic prescription creation device to receive an override of the drug use evaluation alert (Fig. 23, Fig. 24, and col. 11, lines 29-39 of Goetz); and

computer-readable program code for transmitting the override over a network to a prescription processor (Fig. 1, col. 12, lines 51-59, and col. 6, lines 22-26 of Goetz);

wherein the prescription processor, upon receipt of the prescription, attempts to process the prescription and actuates a second drug use evaluation; and if a resultant drug use evaluation alert is correspondent to said override of the user, the prescription processor processes the prescription (col. 11, lines 52 - col. 12, line 10 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

(CC) Claim 46 repeats the same limitations of claim 26, and is therefore rejected for the same reasons given for that claim.

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(DD) Referring to claim 47, Goetz discloses an electronic device configured to create prescriptions, the electronic device including means for querying whether the user desires to override the drug use evaluation alert, the electronic device including means for receiving an override of the drug use evaluation, (Fig. 23 & Fig. 24 of Goetz) the electronic device including means for transmitting the override for the drug use evaluation over a network to a prescription processor (Fig. 6, col. 8, lines 52-67, and col. 11, lines 29-37 of Goetz);

wherein the prescription processor, upon receipt of the prescription, attempts to process the prescription and actuates a second drug use evaluation, and if a resultant drug use evaluation alert is correspondent to said override of the user, the prescription processor processes the prescription (col. 11, line 52 – col. 12, line 10 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

(EE) Referring to claim 48, Goetz discloses means for receiving a reason for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz).

(FF) Referring to claim 49, Referring to claim 49, Goetz discloses computer executable software code stored on a computer readable medium of an electronic prescription creation device comprising the code for generating a graphical user interface, wherein the graphical user interface comprises (col. 12, lines 51-59 & col. 4, lines 50-52; the Examiner interprets "software routine" to be a form of "software code"):

at least one representation querying whether a user desires to override a drug use evaluation alert (col. 11, lines 29-39 of Goetz); and

at least one representation allowing the user to transmit the override over a network (col. 11, lines 29-39 and col. 6, lines 22-26 of Goetz).

Goetz does not disclose transmitting the prescription information directly to a prescription processor.

Lion discloses transmitting the prescription information directly to a prescription processor (col. 5, lines 18-26 of Lion).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lion within Goetz. The motivation for doing so would have been for the pharmacist to receive valid prescription requests (col. 5, lines 26-37 of Lion).

(GG) Referring to claim 50, Goetz discloses at least one representation corresponding to a motive for overriding the drug use evaluation alert (col. 16, lines 42-47 of Goetz). (HH) Referring to claim 90, Goetz discloses wherein the prescription includes information communicating the drug use evaluation alert (col. 11, lines 48-62 of Goetz).

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- 11. Claims 3-8, 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Lion (US 6,330,491 B1) as applied to claims 1-2, 20-21, and 25-26 above, and further in view of Edelson et al. (5,737,539).
- (A) Referring to claims 3-8, Goetz and Lion do not disclose the plurality of representations including: a representation that a patient is no longer taking a conflicting drug, a representation that a patient is stabilized on the drug for the prescription, a representation that a patient is not allergic to the drug for the prescription, a representation that a dosage of the drug is appropriate for a patient's weight, a representation that a dosage of the drug is appropriate for a patient's condition, and a representation that a patient is not pregnant.

Edelson discloses a representation that a patient is no longer taking a conflicting drug (col. 31, lines 39-46 if Edelson; the Examiner interprets "expired prescriptions" to be a form of "no longer taking"), a representation that a patient is stabilized on the drug for the prescription (col. 31, lines 39-46 of Edelson), a representation that a patient is not allergic to the drug for the prescription (col. 31, lines 25-32 of Edelson), a representation that a dosage of the drug is appropriate for a patient's weight (col. 25, line 64 – col. 26, line 10 of Edelson), a representation that a dosage of the drug is appropriate for a patient's condition (col. 2, lines 18-24 of Edelson), and a representation that a patient is not pregnant (col. 25, line 64 – col. 26, line 10 of Edelson).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Edelson within Goetz and Lion. The motivation for doing so would have been to screen for possible unintended adverse outcomes and to provide special precautions regarding a prescribed drug's use (col. 30, lines 58-60 of Edelson).

(B) Referring to claim 22, Goetz and Lion do not disclose the plurality of representations including at least one of the following: a representation that the patient is no longer taking a conflicting drug a representation that the patient is stabilized on the drug for the prescription; a representation that the patient is not allergic to the drug for the prescription; a representation that a dosage of the drug is appropriate for the patient's weight; a representation that the dosage of the drug is appropriate for the patient's condition; a representation that the patient is not pregnant; a representation of a narrow therapeutic drug index; a representation that a concurrent diagnosis prohibits another selection; a representation of a failed therapy; and a representation that the patient is unable to take another selection.

Edelson discloses the plurality of representations including: a representation that the patient is no longer taking a conflicting drug (col. 31, lines 39-46 of Edelson); a representation that the patient is stabilized on the drug for the prescription (col. 31, lines 39-46 of Edelson); a representation that the patient is not allergic to the drug for the prescription (col. 31, lines 25-32 of Edelson); a representation that a dosage of the drug is appropriate for the patient's weight (col. 25, line 64 – col. 26, line 10 of Edelson); a representation that the dosage of the drug is appropriate for the patient's condition (col.

2, lines 18-24 of Edelson); and a representation that the patient is not pregnant (col. 25, line 64 – col. 26, line 10 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Edelson within Goetz and Lion. The motivation for doing so would have been to screen for possible unintended adverse outcomes and to provide special precautions regarding a prescribed drug's use (col. 30, lines 58-60 of Edelson).

(C) Claim 28 differs from method claim 22 by reciting a "computer-readable medium" within its preamble. As per these elements, Edelson's electronic prescription creation system includes a device that can interpret bar-coding (col. 29, lines 35-41 of Edelson). As such, it is readily apparent that Edelson's electronic prescription creation system includes a computer-readable medium.

The remainder of claim 28 repeats the same limitations of method claim 22, and is therefore rejected for the same reasons given above for claim 22, and incorporated herein.

- 12. Claims 51-78, 85, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum (US 6,529,801 B1) in view of NCVHS (http://www.ncvhs.hhs.gov/970416w2.htm).
- (A) Referring to claim 51, Rosenblum discloses a method comprising:

entering via an electronic prescription creation device a prescription for a drug to prescribe to a patient (abstract of Rosenblum);

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viewing on a graphical user interface of the electronic prescription creation device a query of whether the drug is to be dispensed as written instead of a substitutable generic drug (col. 9, lines 10-40 of Rosenblum); and

entering via the prescription creation device an indication that the drug is to be dispensed as written (col. 9, lines 10-40 and Fig. 29B of Rosenblum).

Rosenblum does not expressly disclose entering via the electronic prescription creation device a reason why the drug is to be dispensed as written.

NCVHS discloses dispense as written (DAW) codes created by NCPDP (see pages 2-3 of NCVHS).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

(B) Referring to claims 52-56, Rosenblum does not disclose viewing on the graphical user interface a plurality of representations each corresponding to a motive for dispensing the drug as written, entering via the electronic prescription creation device the reason why the drug is to be dispensed as written including selecting one of the plurality of representations, the plurality of representations including at least one NCPDP dispense as written code, the plurality of representations including a representation that the drug is medically necessary, and the plurality of representations including a representation that a patient requests the drug.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP (see pages 2-3 of NCVHS).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

- (C) Referring to claim 57, Rosenblum discloses entering via the electronic prescription creation device an indication representing that the drug is to be dispensed as written including selecting an icon on the graphical user interface (col. 9, lines 10-40 and Fig. 29B of Rosenblum).
- (D) Referring to claim 58, Rosenblum discloses completing the prescription with the electronic prescription creation device (col. 2, lines 4-7 of Rosenblum).
- (E) Referring to claim 59, Rosenblum discloses the prescription being a paper prescription printed with a printer in communication with the electronic prescription creation device (Fig. 3 of Rosenblum).
- (F) Referring to claims 60-61 and 63-64, Rosenblum does not disclose the paper prescription including indicia thereon communicating the reason why the drug is to be dispensed as written, the indicia including a NCPDP dispense as written code, the electronic prescription including information communicating the reason why the drug is to be dispensed as written, and the information further communicating a NCPDP dispense as written code.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP (see pages 2-3 of NCVHS).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

- (G) Referring to claim 62, Rosenblum discloses the prescription being an electronic prescription (abstract of Rosenblum).
- (H) Referring to claim 65, Rosenblum discloses a method comprising:

entering via an electronic prescription creation device a prescription for a drug to prescribe to a patient (abstract of Rosenblum);

viewing on a graphical user interface of the electronic prescription creation device and entering via the electronic prescription device (col. 16, lines 46-61 of Rosenblum).

Rosenblum does not disclose a plurality of representations each corresponding to a motive for dispensing the drug as written and entering a reason why the drug is to be dispensed as written.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP (see pages 2-3 of NCVHS).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

(I) Claims 66 repeats the same limitations of claim 53 and is therefore rejected for the same reasons given for that claim.

(J) Claim 67 repeats the same limitations of claims 55 and 56 and is therefore rejected for the same reasons given for those claims.

- (K) Claim 68 repeats the same limitations of claims 58 and 62-63 and is therefore rejected for the same reasons given for those claims.
- (L) Claims 69-70 repeat the same limitations of claim 54 and are therefore rejected for the same reasons given for that claim.
- (M) Referring to claim 71, Rosenblum discloses a computer-readable medium having instructions stored thereon, the instructions when executed by an electronic device cause the electronic device to (col. 3, lines 6-36 of Rosenblum):

create a prescription for a drug (abstract of Roseblum).

Rosenblum does not disclose receive from a user of the electronic device a reason why the drug is to be dispensed as written.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP that indicate why the drug is to be dispensed as written (see pages 2-3 of NCVHS).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

- (N) Claims 72 and 74-77 repeat the same limitations of claims 52, 67, 63, and 62 and are therefore rejected for the same reason given for those claims.
- (O) Referring to claim 73, Rosenblum does not disclose the reason for overriding the drug use evaluation alert being at least one of the plurality of representations presented on the graphical user interface.

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NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP that indicate why the drug is to be dispensed as written (see pages 2-3 of NCVHS, specifically DAW code 6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

(P) Referring to claim 78, Rosenblum discloses communicating to a workstation via a network (see abstract of Rosenblum).

Rosenblum does not expressly disclose communicating the reason why the drug is to be dispensed as written.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP that indicate why the drug is to be dispensed as written (see pages 2-3 of NCVHS, specifically DAW code 6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

(Q) Referring to claim 85, Rosenblum does not disclose causing the electronic prescription device to present a plurality of representations each corresponding to a motive for dispensing the drug as written.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP that indicate why the drug is to be dispensed as written (see pages 2-3 of NCVHS, specifically DAW code 6).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS).

(R) Referring to claim 88, Rosenblum discloses computer executable software code stored on a computer readable medium of an electronic device configured to create prescriptions comprising the code for generating a graphical user interface (abstract and col. 3, lines 6-36 of Rosenblum).

Rosenblum does not disclose a plurality of representations each corresponding to a motive for dispensing a drug as written, each of the representations being selectable by a user of the electronic device.

NCVHS discloses a list of dispense as written (DAW) codes created by NCPDP that indicate why the drug is to be dispensed as written (see pages 2-3 of NCVHS, specifically DAW code 6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Rosenblum to include selectable DAW codes for the motivation of using a standard code set that is understood by pharmacists (page 2 of NCVHS) and to provide a user-friendly interface.

- 13. Claims 89, 12, 13, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Simcox (5,992,890).
- (A) Referring to claim 89, Goetz discloses a method comprising:

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entering via an electronic prescription creation device a prescription for a drug (abstract, lines 1-12 of Goetz; the Examiner interprets "medication management system" to be a form of "prescription creation device");

viewing a drug use evaluation alert on a graphical user interface of the electronic prescription creation device (abstract, lines 19-25 & col. 4, lines 50-52 of Goetz);

viewing on the graphical user interface a query of whether a user desires to override the drug use evaluation alert and entering via the electronic prescription creation device an override of the drug use evaluation alert (col. 12, lines 3-10 of Goetz).

Goetz does not disclose creating a paper prescription printed with a printer in communication with the electronic prescription creation device.

Simcox discloses creating a paper prescription printed with a printer in communication with the electronic prescription creation device (Fig. 3 and col. 5, lines 3-25 of Simcox).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Simcox within Goetz. The motivation for doing so would have been to provide a printed copy of the completed prescription for the patient (col. 5, lines 23-25 of Simcox).

(B) Referring to claim 12, Goetz discloses the paper prescription including indicia thereon communicating that the user has overridden the drug use evaluation alert (col. 16, lines 42-47 of Goetz; the Examiner interprets "note" to be a form of "indicia").

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(C) Referring to claim 13, Goetz discloses the indicia including the drug use evaluation alert (col. 16, lines 42-47 of Goetz; the Examiner interprets "describing the interaction" to be a form of "alert").

(D) Referring to claim 91, Goetz discloses a computer-readable medium having instructions stored thereon, the instructions when executed by an electronic prescription creation device cause the electronic prescription creation device to (col. 1, lines 51-59 of Goetz):

create a prescription for a patient (Fig. 20 of Goetz);

present on a graphical user interface of the electronic prescription creation device a drug use evaluation alert (Fig. 23 of Goetz);

present on a graphical user interface a representation that queries whether a user desires to override the drug use evaluation alert (col. 11, lines 29-39 of Goetz); and receive from the user an override of the drug use evaluation alert (col. 11, lines 29-39 of Goetz).

Goetz does not disclose to create a paper prescription printed with a printer in communication with the electronic prescription creation device containing the override.

Simcox discloses to create a paper prescription printed with a printer in communication with the electronic prescription creation device (Fig. 3 and col. 5, lines 3-25 of Simcox).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Simcox within Goetz. The motivation for doing

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so would have been to provide a printed copy of the completed prescription for the patient (col. 5, lines 23-25 of Simcox).

## Response to Arguments

- 14. Applicant's arguments with respect to claims 1, 20, 25, 36, 38, 45, 47, 49, 51, 65, 71, 79, 84, 86, 88, 89, and 91 have been considered but are moot in view of the new ground(s) of rejection.
- 15. Applicant's arguments filed 11/8/05 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 11/8/05.
- (1) Applicant argues that Goetz does not teach or even suggest that an interaction detected by the pharmacist is compared with the user's override before the prescription is processed. Therefore, Goetz contemplates that the pharmacist can override the interaction check without the consent of the physician.
- (A) As per the first argument, the Examiner respectfully submits that at col. 11, line 40 col. 12, line 10 and col. 12, lines 1-9, Goetz discloses the pharmacist utilizing information received from the physician and conducting additional drug evaluations and checking for potential interactions and cautions before prescribing the drug. Goetz also teaches overriding done by the user (i.e., the physician) (see Fig. 23 and Fig. 24 of Goetz). As such, it is readily apparent that Goetz teaches that an interaction detected

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by the pharmacist is compared with the user's override before the prescription is processed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., needing the consent of a physician) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

#### Conclusion

- 16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method for optimizing pharmaceutical prescribing (US 2002/0095314 A1).
- 17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday Friday, 8:30 am 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).